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| APPLICATION NO.  | FILING DATE    | FIRST NAMED INVENTOR     | ATTORNEY DOCKET NO.             | CONFIRMATION NO. |
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| Doreen M. Hogle, Esq. HAMILTON, BROOK, SMITH & REYNOLDS, P.C. Two Militia Drive Lexington, MA 02421-4799 |                |                          | EXAMINER                        |                  |
|  |                |                          | WHISENANT, ETHAN C              |                  |
|  |                |                          | ART UNIT                        | PAPER NUMBER     |
|  |                | ·                        | 1634<br>DATE MAILED: 09/04/2002 | . 7              |

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary    College   |   |                                   | · · · · · · · · · · · · · · · · · · · |  |  |  |  |
|--|---|-----------------------------------|---------------------------------------|--|--|--|--|
| ## Examiner ## Enthan Whisenant, Ph.D.   1634    ## The MAILING DATE of this communication appears on the cover sheet with the correspondence address = Period for Reply    A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE £ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.    ## Examiner of time may be available under the provisions of 37 CFR 1.13(b), In no event, however, may a reply be limited with the correspondence address = 1 the period for reply as pacified above, the newton state of period of sile and the provisions of 37 CFR 1.13(b), In no event, however, may a reply be limited with the period of the period of the communication of the period of the period of the communication of the period of the period of the communication of the period of the communication of the period of the communication of the period of the period of the communication of the period | •   | Application No.                   | Applicant(s)                          |  |  |  |  |
| Ethan Whisenant, Ph.D. 1634  - The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  If the period for riphy specified above is loss than thirty (60) days, and the period by the period days will be considered timely.  If the period for riphy specified above, the menalimar dative pretor will apply within the standary minimum of thirty (30) days will be considered timely.  If the period for riphy is specified above, the menalimar dative pretor will apply within the standary minimum of thirty (30) days will be considered timely.  If the period for riphy is specified above, the menalimar dative pretor will apply within the standary minimum of thirty (30) days will be considered timely.  If the period for riphy is specified above, the menalimar days and all replications, and all replications, and all replications.  If the period for riphy is specified above, the replications are the mailing date of this communication, even if threly field, may reduce all replications.  Application is FINAL.  2b)   | Office Action Summary   |                                   |                                       |  |  |  |  |
| — The MALING DATE of this communication appears on the cover sheet with the correspondence address → Period for Repty  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ½ MONTH(S) FROM THE MALING DATE OF THIS COMMUNICATION.  It is better that the image has evaluate under the provisors of 3 CPR 1.35(g). In no event, however, may a reply be timely filled  If the period for reply appelled above is least than tirty (30) days, are tray within the statutory minimum of thirty (30) days will be considered sheely.  If the period for reply appelled above, the maximum datory period vall applies on which will be considered sheely.  If the period for reply appelled above, the maximum datory period vall applies (30) days are labelled at the communication.  If the period for reply appelled above, the maximum datory period vall applies of the communication, days the considered sheely.  If the period for reply applies the communication of this communication, and this period of the communication.  If the period is CPR 1.75(d).  Status  Status  Responsive to communication(s) filed on  | Office Action Guillinary  |                                   |                                       |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE £ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Examination of time may be arealized to under the provisions of 37 CFR 1.136(s), in no event, however, may a reply be timinely find  - Examination of time may be arealized but which the provisions of 37 CFR 1.136(s), in no event, however, may a reply be timinely find  - If the provide or may specified above, the maximum statistory product will apply and will expire SIX (s) MoNTH'S from the mailing date of this communication.  - If NO pesied for regly is specified above, the maximum statistory product will apply and will expire SIX (s) MoNTH'S from the mailing date of this communication.  - Any reply received by the Office little than three more than after the mailing date of this communication, even if timely find, may reduce any  search placet term adjustment. See 37 CFR 1.704(s).  - Status  1) Responsive to communication(s) filled on  - Any reply received by the Office little than three more than the mailing date of this communication, even if timely find, may reduce any  search placet term adjustment. See 37 CFR 1.704(s).  - Status  1) Responsive to communication(s) filled on  - Any reply received by the Office little than the mailing date of this communication, even if timely find, may reduce any  search placet term adjustment. See 37 CFR 1.704(s).  - Status  1) Responsive to communication(s) filled on  - Status  1) Responsive to communication(s) filled on  - Status  1) Responsive to communication(s) filled on  - Status  1) Responsive to communication for allowance except for formal matters, procedularly filled provided in the mailing date of this communication.  - Status and the search of the mailing date of the communication.  - Status and the search of the sear  | The MAII INO DATE of this communication and   | I                                 |                                       |  |  |  |  |
| THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be seniform early to extension of 37 CPR 13(e). In no event, however, may a reply be timely filed after SIX (8) MCNTHS from the mailing date of this communication.  If the periods may be specified used to fine to communication of the six (8) MCNTHS from the mailing date of this communication.  Falure to reply within the set or extended pariod for reply will. by stantor, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office stort the three mornists after the mailing date of this communication, even if timely filed, may reduce any seared patent term adjustment. See 37 CPR 1.70(b).  Status  1) Responsive to communication(s) filed on   |   |                                   |                                       |  |  |  |  |
| 1)  Responsive to communication(s) filed on  2a)  This action is FINAL. 2b)  This action is non-final.  3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4)  Claim(s)   | <ul> <li>THE MAILING DATE OF THIS COMMUNICATION.</li> <li>Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul> |                                   |                                       |  |  |  |  |
| 2a  This action is FINAL. 2b  This action is non-final.  3  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4)  Claim(s) 1-32 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5  Claim(s) is/are allowed.  6  Claim(s) is/are objected to.  8)  Claim(s) 1-32 are subject to restriction and/or election requirement.  Application Papers  9)  The specification is objected to by the Examiner.  10)  The drawing(s) flied on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  11)  The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.  If approved, corrected drawings are required in reply to this Office action.  12)  The oath or declaration is objected to by the Examiner.  Priority under 35 U.S.C. §§ 119 and 120  13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a)  All b) Some * c) None of:  1.  Certified copies of the priority documents have been received in Application No  3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  *See the attached detailed Office action for a list of the certified copies not received.  14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  Attachment(s)  1  Interview Summary (PTO-413) Paper No(s)  5  Notice of Informal Patent Application (PTO-152)  | <u></u>   |                                   |                                       |  |  |  |  |
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| 4a) Of the above claim(s) is/are withdrawn from consideration.  5) □ Claim(s) is/are allowed.  6) □ Claim(s) is/are rejected.  7) □ Claim(s) is/are objected to.  8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.  Application Papers  9) □ The specification is objected to by the Examiner.  10) □ The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  11) □ The proposed drawing correction filed on is: a) □ approved b) □ disapproved by the Examiner.  If approved, corrected drawings are required in reply to this Office action.  12) □ The oath or declaration is objected to by the Examiner.  Priority under 35 U.S.C. §§ 119 and 120  13) □ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) □ All b) □ Some * c) □ None of:  1. □ Certified copies of the priority documents have been received in Application No  3. □ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  14) □ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  Attachment(s)  1 □ Interview Summary (PTO-413) Paper No(s)  Attachment(s)  1 □ Notice of References Cited (PTO-892)  2 □ Notice of Draftsperson's Patent Drawing Review (PTO-948)   | · <u> </u>  |                                   |                                       |  |  |  |  |
| 6) ☐ Claim(s) is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☒ Claim(s) is/are objected to. 8) ☒ Claim(s) is/are objected to estriction and/or election requirement.  Application Papers 9) ☐ The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.         Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.         If approved, corrected drawings are required in reply to this Office action. 12) ☐ The oath or declaration is objected to by the Examiner.  Priority under 35 U.S.C. §§ 119 and 120  13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).         a) ☐ All b) ☐ Some * c) ☐ None of:         1. ☐ Certified copies of the priority documents have been received in Application No          3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).         a) ☐ The translation of the foreign language provisional application has been received.  15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  Attachment(s)  10 ☐ Notice of References Cited (PTO-892)  21 ☐ Notice of References Cited (PTO-982)  22 ☐ Notice of Interview Summary (PTO-413) Paper No(s)  | /= · · · · · · · · · · · · · · · · · · ·  |                                   |                                       |  |  |  |  |
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| If approved, corrected drawings are required in reply to this Office action.  12) The oath or declaration is objected to by the Examiner.  Priority under 35 U.S.C. §§ 119 and 120  13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some colon None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No.  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  Attachment(s)  1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413) Paper No(s).  5) Notice of Informal Patent Application (PTO-152)  |   |                                   |                                       |  |  |  |  |
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|  | 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)   | 5) Notice of Informa              |                                       |  |  |  |  |

## **ELECTION/RESTRICTION**

1. Claim(s) 1-32 is/are pending in the application.

## **SEQUENCE RULES**

2. This application complies with the sequence rules and the sequences have been entered by the Scientific and Technical Information Center.

## **ELECTION/RESTRICTION**

- **3.** Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Claims 1-23 drawn to a method of detecting low frequency mutations in a target sequence, classified in at least Class 435, subclass 6.
  - II. Claims 24-32 drawn to a method of preparing a plurality of target-enriched DNA samples, classified in at least Class 536, subclass 25.3.
- **4.** The inventions are distinct, each from the other for the following reasons.

**Inventions I and II** are unrelated and patentably distinct methods with different goals, different intermediate steps and different end results (see MPEP § 806.04, MPEP § 808.01). Most importantly, note that a search for one will not necessarily result in a search for the other.

**5.** Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the necessity for non-coextensive literature searches, restriction for examination purposes as indicated is proper.

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- **6.** Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- **6.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.

ETHAN C. WHISENANT PRIMARY EXAMINER